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510(k) Summary
Coeur Front Load Injector Retrofit Kit
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Proprietary Name: Coeur Front Load Injector Retrofit Kit

Common Name: Injector Face Plate

Classification Name: Injector and Syringe, Angiographic

Predicate Devices: Coeur Front Load Injector Turret and Front Load Syringe
Medrad MCT and MCT Plus Injector with Front Load Syringe

Device Description:

The Coeur Front Load Retrofit Kit consists of two accessory pieces for use with Medrad MCT and MCT Plus Injector Systems and older models of Medrad injectors upgraded by Medrad to resemble the MCT and MCT Plus. The kit contains a face plate and ram tip extension that allow easy use of the Coeur 200 mL Front Load Syringe on the modified versions of Medrad injectors. This premarket notification describes the Coeur Face Plate Retrofit Kit, which is a modification of the Coeur Front Load Injector Turret, which allows use of the Coeur 200 mL Front Load Syringe on older models of Medrad injectors.

The Face Plate uses a standard bayonet mount to attach directly onto the Medrad injector-base on the MCT and MCT Plus injectors. The ram tip extension is then attached to the existing ram tip and tightened into place to prevent slippage. Once in place, the Coeur 200 mL Front Load Syringe may be used easily on the injectors.

Intended Use:

The Coeur Front Load Injector Retrofit Kit is intended to be used with Medrad MCT and MCT Plus Injectors to hold the Coeur 200 mL Front Load Syringe in place in front of the Injector Ram during the injection of contrast media into the vascular system for diagnostic purposes.

Technological Characteristics:

Materials: The Coeur Front Load Injector Retrofit Kit contains a machined aluminum face plate, a stainless-steel ram tip, and two brass-tipped set screws.

Packaging / Sterilization: Retrofit Kit is packaged individually in a polyethylene bag inside a corrugated cardboard outer carton. The face plate does not come into contact with the fluid path during operation, and is not a sterile device.

Performance Test Data / Conclusions:

Verification data was summarized to demonstrate that the Coeur Front Load Injector Retrofit Kit components could be produced to specification. Additionally, simulated clinical usage tests showed that a Medrad injector fitted with the Retrofit Kit and the Coeur 200 mL Front Load Syringe performed as well as the Medrad injector fitted with the previously cleared Coeur Front Load Injector Turret and Coeur 200 mL Front Load Syringe.